



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 8, 2020

Mr. Jason Ducan
Regulatory Affairs Specialist for,
West Argo, Inc.
1855 S. Mt. Prospect Road
Des Plaines, IL 60018

Subject: PRIA Label Amendment – To add EVP Labeling Claims
Product Name: ZZZ Disinfectant
EPA Registration Number: 4959-16
Application Date: July 8, 2020
Decision Number: 564495

Dear Mr. Ducan:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is (small non-enveloped, large non-enveloped, enveloped).
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against (identify label viruse(s)) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Assurance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at Leavy.Karen@epa.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read 'J. Varco', is positioned above the typed name and title.

Joseph Varco
Acting Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs

Enclosure

ZZZ™ DISINFECTANT IS A CONCENTRATED BROAD SPECTRUM IODOPHOR FOR USE AS A ONE-STEP
CLEANER-DISINFECTANT AND NO-RINSE SANITIZER IN:
• Hospitals and Clinics • Food Processing Plants • Dental Offices • Gloved Hand Sanitizer
• Schools and Institutions • Nursing Homes • Kitchens And Lunch Rooms • Restrooms
• VIRUCIDE*, BACTERICIDE, FUNGICIDE
Meets OSHA's Bloodborne Pathogens Act requirements



KEEP OUT OF REACH OF CHILDREN
MANTENER FUERA DEL ALCANCE DE LOS NIÑOS



**PRECAUTIONARY STATEMENT:
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

DANGER: Corrosive. Causes irreversible eye damage. Wear goggles or face shield when handling this product. Harmful if swallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using toilet. Remove contaminated clothing and wash before reuse.



ENVIRONMENTAL HAZARDS: This product is toxic to fish and aquatic organisms. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.
STORAGE: Keep container closed when not in use. Do not store below 25°F or above 100°F for extended periods.
PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying.
5 gallon or less containers - Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning if available. If not, puncture and dispose of in a sanitary landfill, or incineration, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Capacity greater than 5 gallon containers - Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning if available. If not, puncture and dispose of in a sanitary landfill, or incineration, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced into the body, either into or in contact with the bloodstream or normally sterile areas of the body or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.
Not for Residential Use.
The color of a ZZZ™ Disinfectant solution is proportional to the titratable iodine concentration. Prepare a fresh solution daily, or when there is a noticeable change in its rich amber color, or more often if the solution becomes diluted or soiled.
Used as directed, ZZZ™ Disinfectant is effective in hard water (up to 400 ppm as CaCO₃) and in 5% organic serum load against the following viruses, bacteria and pathogenic fungi: *Vaccinia**, *Herpes Simplex Type 1**, *Influenza A2/Japan 305**, *Hepatitis B** and *Norovirus*; bactericidal against *Salmonella enterica*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *E. Coli*; fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus).
ZZZ™ Disinfectant is effective against *Listeria monocytogenes* on pre-cleaned food contact surfaces.
Used in hard water (up to 400 ppm CaCO₃), **ZZZ™ Disinfectant** is effective against the HIV-1 virus on pre-cleaned environmental surfaces and objects previously soiled with blood or other body fluids.
2056-D0317-EPA (Directions continued on right panel.)

FOR INDUSTRIAL, INSTITUTIONAL AND AGRICULTURAL USE

ZZZ™ Disinfectant

AUTHORIZED BY USDA FOR USE IN FEDERALLY INSPECTED
MEAT, POULTRY AND EGG PROCESSING PLANTS

ACTIVE INGREDIENT:
Iodine*..... 1.88%
INERT INGREDIENTS..... 98.12%
Total100.00%
*from Polyoxyethylene alcohol – iodine complex and Polyethoxypolypropoxyethanol-iodine complex

EPA Reg. No. 4959-16 EPA Est. No. _____

See left panel for additional precautions

FIRST AID	
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes. Then continue rinsing. Call a Poison Control Center or doctor for treatment advice.
IF SWALLOWED:	Call a Poison Control Center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
IF INHALED:	Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.
Have product container or label with you when calling a Poison Control Center or doctor or going in for treatment. You may also contact 1-800-424-9300 for emergency treatment information. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

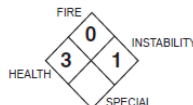
FOR ADDITIONAL INFORMATION CONSULT YOUR WEST AGRO, INC. REPRESENTATIVE
OR SAFETY DATA SHEET.

DOT DESCRIPTION

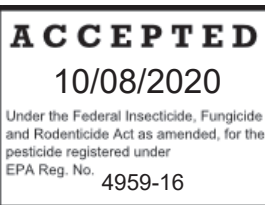
UN3264

Corrosive liquid, acidic, inorganic, N.O.S.
(contains Phosphoric Acid), 8, PG II

HAZARD RATING
4-EXTREME
3-HIGH
2-MODERATE
1-SLIGHT
0-INSIGNIFICANT



West Agro, Inc.
11100 N. Congress Ave.
Kansas City, Missouri 64153
MADE IN USA / MADE IN CANADA



ONE-STEP CLEANING AND DISINFECTING:

This product may be used to clean and disinfect hard nonporous surfaces in operating areas, patient rooms, floors, walls, countertops, restrooms, shower areas, refuse containers, bed frames, morgues, laboratories, cafeterias, animal rooms, cages and other hard nonporous surfaces. Before applying disinfecting solution, food products and packaging materials must be removed from the room or carefully protected. Remove visible soil deposits before applying the disinfecting solution. Using a solution of 4.8 fl. oz. **ZZZ™ Disinfectant** per 10 gallons of warm water (68°F, 20°C or warmer), immerse objects in disinfecting solution, or apply solution with a mop, sponge or cloth. Where appropriate, use a mechanical sprayer to produce coarse spray. Allow a 10 minute contact time with disinfecting solution. All food contact surfaces must be rinsed with potable water before reuse. Floors, walls and all other non-food contact do not require rinsing before reuse.

NOTE: When using **ZZZ™ Disinfectant** against the following viruses, bacteria and pathogenic fungi: *Vaccinia**, *Herpes Simplex Type 1**, and *Influenza A2/Japan 305**, *Salmonella enterica*, *Pseudomonas aeruginosa*, *E. Coli*, *Trichophyton mentagrophytes*, in a solution of cold water (as low as 41°F, 5°C), increase use to 9.6 fl. oz. per 10 gallons water. When using **ZZZ™ Disinfectant** against the following virus: *Norovirus*, increase use to 9.6 fl. oz. per 10 gallons of water.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1). (Associated with AIDS.)

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES AND OBJECTS PREVIOUSLY SOILED WITH BLOOD OR OTHER BODY FLUIDS.

PERSONAL PROTECTION: Clean up should always be done wearing protective latex gloves, gowns, masks and eye protection. (Specific barrier protection items to be used when handling items soiled with blood or bodily fluids are disposable gloves, gowns, masks, or eye coverings.)

CLEANING PROCEDURE: Blood and other body fluids (containing HIV-1) must be thoroughly cleaned from surfaces and objects before application of this product. Thoroughly wet hard surfaces with a solution of 4.8 fl. oz. **ZZZ™ Disinfectant** per 10 gallons of water. Completely immerse objects in the disinfecting solution; avoid entrapment of air bubbles. Allow at least 10 minutes contact time.

CONTACT TIME: This contact time will not control other common types of viruses* and bacteria listed on this label.
DISPOSAL OF INFECTIOUS MATERIAL: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

TO CLEAN AND DISINFECT TOILET BOWLS AND URINALS: Flush toilet. Add 1.5 fl. oz. of **ZZZ™ Disinfectant** directly to toilet bowl. Brush to cover all bowl surfaces including under the rim. Allow disinfectant to remain for at least 10 minutes. Flush toilet. Rinse metal parts with water after disinfecting to prevent corrosion.

SANITIZING PREVIOUSLY CLEANED FOOD CONTACT SURFACES: Sanitize previously cleaned and rinsed hard, non-porous surfaces such as glass, metal, plastic and porcelain with a solution containing 1.5 fl. oz. of **ZZZ Disinfectant** per 10 gallons of water. Spray or immerse equipment with sanitizing solution and allow 1 minute of contact time. Drain solution from equipment; do not rinse. **ZZZ™ Disinfectant** used at 1.5 fl. oz. per 10 gallons of water contains 25 ppm titratable iodine and does not require a final rinse with potable water in accordance with Federal Food Additive Regulation 178.1010.

SANITIZING GLASSES, DISHWARE, POTS, PANS, AND UTENSILS IN FOOD SERVICE OPERATIONS:

1. Pre-flush or pre-scrape equipment and utensils. If needed, pre-soak to remove visible food particles and soil.
2. Wash equipment and utensils in lukewarm water that contains an adequate amount of a good detergent or cleaner. Keep this water clean by frequent changing.
3. Rinse equipment and utensils free of wash water prior to sanitization.
4. Sanitize equipment and utensils by immersing them in a solution of 1.5 fl. oz. **ZZZ™ Disinfectant** per 10 gallons of lukewarm water (provides 25 ppm titratable iodine). Allow one minute contact time (or longer if required by local sanitation codes). Fresh solution should be prepared daily or more often if the solution becomes diluted or soiled. Use an approved iodine test kit to check for proper concentrations.
5. After required contact time of one minute or more, allow equipment and utensils to adequately drain. Do not rinse before use.

GLOVE SANITIZING DIRECTIONS: To prevent cross contamination gloves must be sanitized prior to entering or re-entering those areas. Remove visible soil. Then dip gloved hand in a use-solution of 1.5 fl. oz. of **ZZZ™ Disinfectant** per 10 gallon of water so that there is enough sanitizing solution to cover the gloved area. Allow gloved hands to remain wet for at least 60 seconds. No potable water rinse is required. Change the solution in the bath at least daily or more often if the solution appears visibly diluted or soiled.

EMERGING VIRAL PATHOGEN CLAIMS (Note to Reviewer: None of the language in this section is to appear on any final printed label.)

This product qualifies for emerging viral pathogen claims per EPA's "Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens Not on EPA-Registered Disinfectant Labels" when used according to the appropriate directions for use, as indicated below.

This product meets the criteria to make claims against emerging viral pathogens from the following viral categories: Enveloped viruses
Large non-enveloped viruses

For an emerging viral pathogen that is a(n)...	...follow the use directions for the following organisms on the label:
Enveloped virus	Norovirus (Feline Calicivirus)
Large non-enveloped virus	Norovirus (Feline Calicivirus)

The following statements may be used only in off-label communications as described in EPA's Emerging Viral Pathogens guidance, and only under the conditions outlined in that guidance:

(Product name) has demonstrated effectiveness against viruses similar to (insert name of emerging virus) on hard, nonporous surfaces. Therefore, (product name) can be used against (insert name of emerging virus) when used in accordance with the directions for use against Norovirus (Feline Calicivirus) on hard, nonporous surfaces. Refer to the [(CDC) {OIE}] website at (insert pathogen-specific website address) for additional information.

USE DILUTION TABLE	
<u>ZZZ™ Disinfectant / Water</u>	<u>TITRATABLE IODINE</u>
1.5 fl. oz to 10 gal.	25 ppm
4.8 fl. oz to 10 gal	80 ppm
9.6 fl. oz to 10 gal.	160 ppm

CHEM-TREC EMERGENCY # 1-800-424-9300

NET CONTENTS:LOT NO: